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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,981

07/31/2003

George Martinez

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2212

37374

7590

11/07/2008

INSKEEP INTELLECTUAL PROPERTY GROUP, INC  
2281 W. 190TH STREET  
SUITE 200  
TORRANCE, CA 90504

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

11/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

inskeepstaff@inskeelaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/631,981	<b>Applicant(s)</b> MARTINEZ, GEORGE	
	<b>Examiner</b> ELIZABETH HOUSTON	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Terminal Disclaimer***

1. The terminal disclaimer filed on 07/31/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 11/089,207 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka (US 2002/0169473) in view of Rosenthal (US 7,006,904).

4. Sepetka discloses a vaso-occlusive device implant, comprising:  
an elongate, flexible, filamentous inner element (352); a non-metallic intermediate element coaxially surrounding the inner element and in intimate contact therewith substantially along the length of the inner member (Para [0164] where the intermediate element is drug coating); and an outer element coaxially surrounding the intermediate element and in intimate contact therewith (354), the outer element defining a gap or opening through which the intermediate element is exposed and through which the intermediate element is capable of swelling (see for example Figs 62-64, 67, 68). The

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inner element comprises a microcoil (in the sense that micro is extremely small and therefore not being given patentable weight). The outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed. The proximal and distal end sections of the outer element are respectively attached to the distal and proximal ends of the inner element (although not necessarily fixedly attached, the coils are attached in the sense that are joined together as one element). Each of the proximal and distal end sections of the outer element includes a close-wound helical coil section (for example Fig. 67, 68).

5. Sepetka does not disclose the intermediate element being an expansile polymeric material that is a hydrogel. Sepetka does disclose that an intermediate element that is for providing drug delivery. However, Rosenthal teaches an expansile polymeric material element that is for providing drug delivery and consists essentially of hydrogel (C3:L37-39; C4:L6, 11). The hydrogel is *capable* of expanding at a controlled rate to fill an aneurysm (C1:L57-59; C2:L9-31; C3:L59-C4:L14; and C4:L53-64 indicate that the expansion of the hydrogel is controlled by exposure to a triggering mechanism or agent). The hydrogel expands in response to change in temperature or pH (C 3: L33-41; C4:L10-14).

6. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention, namely a way of delivering a drug in a controlled manner via the use of hydrogel and a triggering mechanism. The

use of hydrogel and a triggering mechanism allows the user to have full control over timing of the drug delivery thus preventing the drug from being released prematurely. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

7. The modified device would meet the limitation that the intermediate element, when expanded, extends through the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments. Sepetka discloses the use of one coil as the outer element (Para [0164] *one or more secondary coils*) It is well known in the art that hydrogels can expand up to 600 times their original size. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01).

8. Sepetka in view of Rosenthal does not disclose a coupling element attached to the proximal end of the inner element and to the proximal end of the outer element. It would have been well within the skill of the ordinary artisan to incorporate a coupling element at the proximal ends of the coils since it is old and well known to use coupling elements (i.e. welds, radiopaque markers, sutures) in medical implants having coaxially surrounding elements (i.e. embolic coils, stent-grafts, embolic filters). The common knowledge or well-known in the art statement is taken to be admitted prior art because applicant has failed to traverse the examiner's assertion of official notice

***Response to Arguments***

9. Applicant's arguments filed 07/31/08 have been fully considered but they are not persuasive. Applicant states that the coating is not an expansile element because Rosenthal discloses a balloon which would be the expansile element. It is irrelevant whether the prior art chooses to incorporate an additional expansile element (balloon) as applicant asserts. The coating is in and of itself an expansile element by the sheer fact that it expands. Although the prior art contains additional structure not required by Applicant's invention, it must be noted that the prior art does disclose the invention as claimed. Applicant goes on to explain that an expansile element would grow without the assistance of a balloon. Examiner asserts that the expansile element being a coating does in fact grow without the assistance of the balloon. Although the prior art teaches the method of first expanding the balloon prior to expanding the hydrogel and releasing the drug, expanding the balloon is not required for the step of expanding the hydrogel to occur. As stated above in the rejection, Rosenthal does in fact disclose that the hydrogel can expand at a controlled rate by the use of a triggering mechanism, thus providing the advantage of preventing premature delivery of the drug.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731